

510(k) Summary

10823411

AUG 29 2008

Submitter's Name: Eigen Inc.
 Submitter's Address: 13366 Grass Valley Avenue, Grass Valley, CA 95945
 Submitter's Telephone: 530-274-1240
 Contact Name: Animesh Khemka
 Date Summary was Prepared: July 23, 2008
 Trade or Proprietary Name: DSA 2000ex
 Common or Usual Name: Digital Subtraction Angiography
 Classification Name: System, Image Processing, Radiological, LLZ
 Picture Archiving and Communications, 21CFR 892.2050

Predicate Devices:

Device Name	510(k) Number
Digital 8	K901956
DSA 2000	K063846

Description of the Device and Summary of the Technological Characteristics

The DSA 2000ex device is used in vascular imaging applications. During X-ray exposures, the DSA 2000ex is used to acquire video images from the video display chain provided by the X-ray manufacturer's system. The images are stored in the DSA 2000ex solid state memory, and written to the hard disk medium. Images are processed in real-time to provide increased image usability. The processing is primarily subtraction, but also includes window and level adjustments, as well as optional noise reduction, landscaping, image rotation and pixel shifting. The Eigen DSA 2000ex device is used in X-ray cardiology and radiology labs to enhance diagnostic capabilities of radiologists and cardiologists, with minimal intervention required by users to perform basic capture, playback, and archiving functions. Additional functions include allowing measurements to be made for quantizing stenosis and guidance of catheters in the Roadmapping mode.

Substantial Equivalence

The Eigen DSA 2000ex is substantially equivalent to other Eigen imaging devices: the Digital 8 and DSA 2000. The DSA 2000ex is a modification of Eigen's DSA 2000 cleared under special 510(k) # K063846 and Eigen's Digital 8, which was cleared under 510(k) # K901956. The modifications made to the DSA 2000 and Digital 8 do not alter the intended use or the fundamental scientific technology of the device.

The DSA 2000ex and its predicates (the Digital 8 and DSA 2000) enhance and process images by performing the following functions:

- Noise Reduction
- Window/Level Feature
- Edge Enhancement
- Image Subtraction
- Still Image Display
- X-ray Lab Command Interface
- X-ray Lab Video Interface
- Data Archiving
- Data and Space Management
- Study Information (e.g., patient, site, and date)
- Configuration Menu
- Still Image Acquisition and Display
- Sequence Image Acquisition and Display
- Automated Contrast
- Landscaping
- Pixel Shifting
- Modality Work-List Support
- Mix (also called Roadmapping)
- Quantification (also called Quantitative Coronary Angiography (QCA))

The DSA 2000ex device also offers the additional feature of image rotation which is not in the predicate devices.

Testing and Performance Data

All product and engineering specifications were verified and validated. Test images as well as test phantoms incorporating simulated stenosis were developed and used to verify system performance through verification, validation and benchmarking.

Conclusion

The results of comparing the intended use, function, technological characteristics, mode of

operation and specifications of the DSA 2000ex with those of the predicate devices demonstrate that the DSA 2000ex is substantially equivalent to existing products in the market today.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 29 2008

Eigen, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K082341

Trade/Device Name: DSA 2000ex
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving and Communications System
Regulatory Class: II
Product Code: LLZ
Dated: August 14, 2008
Received: August 15, 2008

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K082341

Indications for Use

510(k) Number (if known): pending

Device Name: "DSA 2000ex"

Indications for Use:

The DSA 2000ex device is used in vascular imaging applications. During X-ray exposures, the DSA 2000ex is used to acquire video images from the video display chain provided by the X-ray manufacturer's system. The images are stored in the DSA 2000ex solid state memory, and written to the hard disk medium. Images are processed in real-time to provide increased image usability. The processing is primarily subtraction, but also includes window and level adjustments, as well as optional noise reduction, landscaping, image rotation and pixel shifting. The Eigen DSA 2000ex device is used in X-ray cardiology and radiology labs to enhance diagnostic capabilities of radiologists and cardiologists, with minimal intervention required by users to perform basic capture, playback, and archiving functions. Additional functions include allowing measurements to be made for quantizing stenosis and guidance of catheters in the Roadmapping mode.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices510(k) Number EIGEN INC. K082341
SPECIAL 510(K) - DSA 2000ex
JULY 23, 2008

Concurrence of CDRH, Office of Device Evaluation (ODE)

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